

Innovative optical techniques for intraoperative anatomical guidance : surgical navigation beyond the limits of the human eye

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Valorization addendum

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This chapter is intended to take a brief look upon the return of investment prospects for society from the knowledge gathered during this PhD-trajectory. For clarification, first a few terms will be defined that are frequently used in this chapter:

- *Valorization* is the use, for socio-economic purposes, of the results of research financed by public authorities. It represents society's direct and indirect return on the public sector's investment in research and development. More recently, the growing emphasis on open innovation has strengthened the cooperation between public research centers, universities and the business sector.
- *Knowledge valorization* refers to the utilization of scientific knowledge in practice. Examples include developing a product or a drug, or applying scientific knowledge to improve an existing system or process. The term knowledge valorization, in turn, is related to the term innovation.
- *Innovation* means converting new inventions to reality, in other words: applying inventions to create a product or process that indeed has a positive societal impact. Thus, in fact, an invention can only be considered an innovation if it is successfully applied and widely adopted in practice.
- History learns that many innovations were initiated by serendipity¹ (valuable result by fortunate coincidence). One might argue that it would be worth thinking about how to increase the chance of indeed producing an innovation. Sheer luck itself cannot be forced, just like mankind cannot directly force a seed to sprout. But in both cases, optimizing the environmental preconditions increases the chance of success.
- An *innovation eco-system* is a research environment that helps to identify the right problems to work on, systematically looks for solutions, and once these are found then encourages and facilitates to complete the road to an actual product.

Hereafter the eco-system in which this thesis was constructed will be described, then the societal and economical relevance of introducing optical techniques in surgery will be addressed, and finally a perspective on knowledge utilization will be given.

Description of the eco-system for the research conducted in this thesis

This thesis focused on two optical techniques for application in surgery: near-infrared fluorescence imaging (using exogenous contrasts) and diffuse reflectance spectroscopy (based on endogenous contrasts). The focus of the research conducted on near-infrared fluorescence laparoscopy was primarily guided by the researchers and medical

specialists from the university medical center. With the resulting outcome of the various (pre)clinical studies and feedback from the end-users, the industrial endoscopic device partner is then able to further optimize the already commercially available laparoscopic fluorescence imaging apparatus (including both hardware and software), the industrial fluorescence contrast partner is helped with preclinical validation of its fluorophore towards future clinical application.

The investigations on diffuse reflectance spectroscopy form an early stage of discovering useful endogenous contrasts for selective tissue-enhancement. This work was conducted as part of the *van 't Hoff Program for Medical Photonics*. This shared research program, coordinated by TNO (Netherlands Organization for Applied Scientific Research), was named after Van 't Hoff, a famous Dutch chemist and winner of the first Nobel Prize for chemistry in 1901. The program is designed to be an innovation ecosystem in which multiple parties work together to make new knowledge applicable more quickly. It is focused upon Photonics in Medicine, because Photonics is regarded as a so-called *Key Enabling Technology*². The European Union also regards developments in scanning, sensing and imaging of crucial importance for medical and healthcare activities to keep competitive and create new markets³.

For “discovery-phase” research the following issues applies:

- Complex and expensive research is needed to solve critical issues;
- Multiple applications by different parties can be expected (all based on the same knowledge base), especially if these parties also have comparable research questions;
- Simultaneous implementation of these applications increases the chance of success of the individual applications, and the synergetic effect is greater than the sum of its parts, thereby enhancing the societal impact and efficiency.

The aforementioned research program combines these points by bringing together key stakeholders to create an innovation ecosystem, ranging from research organizations to equipment and product manufacturers, from hospitals to foundations (see Figure 1).

The van 't Hoff Program: an innovation ecosystem consisting of research organizations, medical industry, key opinion clinicians from leading hospitals and foundations. This approach matches with the EU Council conclusions on innovation in the medical device sector: encourage better consideration of the needs of patients and healthcare professionals in the design process of medical devices and promote early dialogue between manufacturers, scientific and clinical experts, competent authorities and, where appropriate, notified bodies regarding ‘new products’ in particular, and their classification⁴.

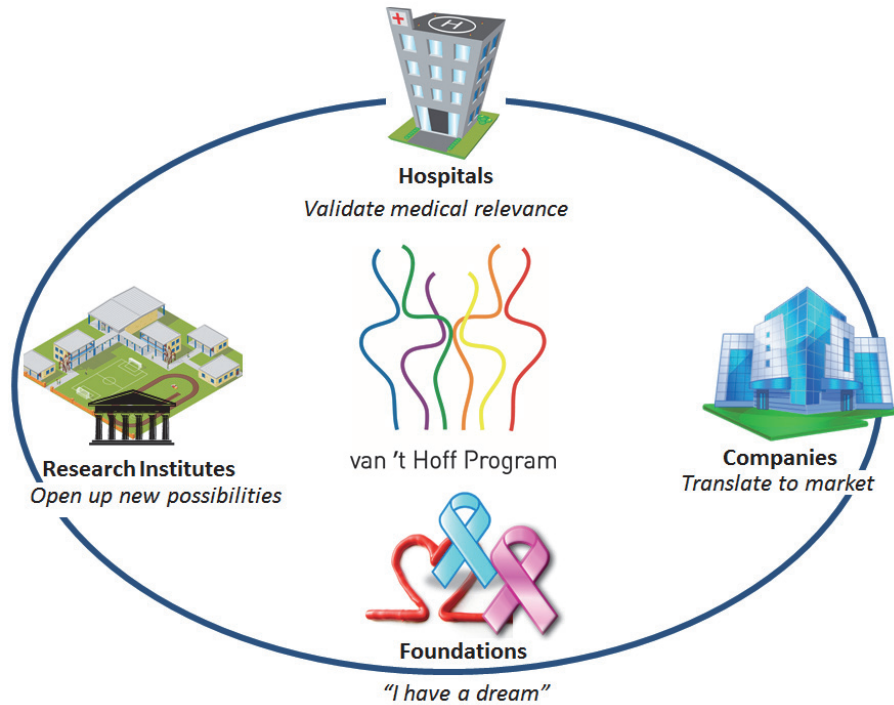


Figure 1 The aforementioned research program

This public-private collaboration is aimed at gathering knowledge and data that will help patients benefit from the potential advantages of optical spectroscopy. By examining the issues and addressing the unknowns together, the program shares the cost and risk factors associated with early phases of development. Each partner in this open innovation platform contributes specific knowledge and expertise to achieve a common goal: optimizing the use of optical spectroscopy in medicine. Risks, costs, facilities and data are shared between all participants, so that advancements can be made more effectively.

This approach provides a solid base that outlines the basic principles of how the technology works, and enables each individual industrial partner to use those principles for application in their product development process. This structure matches with the intention of the European Union to stimulate *Responsible Research and Innovation* that bridges the gap between science and society⁵.

Societal and economical relevance of introducing optical techniques in surgery

As outlined in **Chapter 11** of this thesis, it is likely that by developing and ultimately implementing innovative optical techniques (either near-infrared fluorescence imaging or diffuse reflectance spectroscopy) for intraoperative anatomical guidance, surgeons will benefit from improved (and perhaps even earlier) detection of vital anatomical structures.

In this context a visionary passage from Koninckx et al.⁶, describing a crave for such tools, can be cited: *“Consider that on a separate screen side by side, or even better on the same screen, the vascularization pattern or the fluorescence of a cancer and its metastasis or of the smaller endometriosis lesions would be clearly visible. Consider what would happen to nerve sparing surgery when camera intelligence will show the difference between fibrosis and a nerve. Ureters today can be visualized with illuminated stents, but this is cumbersome and expensive; consider that the camera would recognize the ureter”*. At least two of these visions have come closer to becoming reality, with this thesis.

The developments described in this thesis can (over time) facilitate critical decision-making during surgery, which can result in safer and more efficient surgical dissection. With these projected developments a positive impact on the society – in the first place the patients undergoing surgery – and the economy is foreseen. Improved safety of the patient, in terms of a reduced risk of iatrogenic tissue injury, is in that perspective very relevant.

Enhanced intraoperative nerve detection (investigated in **Chapter 9**) could be beneficial for all kinds of surgical procedures. For example in abdominal surgical procedures preventing injury to autonomic pelvic nerves, improves functional outcome (decrease of the rate of sexual and urinary dysfunctions)⁷ and thereby the quality of life of the patient.

When higher procedural safety and efficiency can be achieved, health-care costs could be reduced by avoiding costly re-operations and thereby re-admission to or longer stay in the hospital, for e.g. repair of a ureteral injury or a common bile duct injury.

For example, Andersson et al conducted a cost-analysis regarding iatrogenic bile duct injury following cholecystectomy in a Scandinavian study population⁸. They conclude that the estimated overall costs for the society for the management of both minor and major bile duct injuries would be between 470,000 and 600,000 EURO per million inhabitants annually.

When certain routine surgical procedures can be performed faster, as a consequence of earlier identification of vital anatomical structures (e.g. as shown by the feasibility study

on early biliary tract delineation using near-infrared fluorescence cholangiography, **Chapter 3**), this can also lead to a cost reduction. In a time of cut-backs on health-care costs, such cost-reduction is of great economical relevance and this can very well be achieved by implementation of innovative optical techniques in the operating room of the future.

Moreover, besides for technicians (medical technologists) and medical specialists (e.g. surgeons), the results of this thesis are also of interest for patients and patient societies. It can create awareness for the general public that there is a realistic hope for better intraoperative detection of vital tissue structures, which can result in safer and more efficient surgical procedures.

Another interesting fact: since 2002 the health care sector is the most important sector of employment in the Netherlands, and the proportion of health care in total employment is still growing. Altogether there are about 870,000 jobs in this sector. Although many highly educated people are working in health care, the number of jobs for highly educated persons itself is not increasing. An increase of highly technical jobs is mainly found in the development of drugs and medical devices. These categories are particularly interesting for the Netherlands, as these can also strengthen our export position⁹.

Perspective on knowledge utilization

From the scope of this thesis, exploration of new intraoperative optical techniques and development of enhanced visualization chains for both open and endoscopic surgery is a goal of the project. As a matter of fact, the exploration of optical imaging/spectroscopy techniques might ultimately be interesting for all camera-linked interventions in medicine. In this way the entire medical community can benefit.

This thesis offers some new insights on medical photonics and hopefully there will follow next steps to make medical photonics contribute to patients' well-being.

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